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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,894	08/24/2001	Richard T. Reel	4727	3333

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MILA KASAN, PATENT DEPT.
APPLIED BIOSYSTEMS
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FOSTER CITY, CA 94404

EXAMINER

OLSEN, KAJ K

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,894

Applicant(s)

REEL ET AL.

Examiner

Kaj K Olsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 14-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 14-25 remain withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).
4. Claims 1-4, 8, 9, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann (USP 4,911,806) in view of Dahms (USP 4,124,470).
5. With respect to claim 1, Hofmann discloses an analyte manipulation device for moving polarizable analyte of interest that comprises two coextensive, elongated, electrically-conductive members (14, 16) disposed in a fixed, spaced relation within a sample holder 18 (fig. 1, and col.

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4, lines 64-66). Hofmann also discloses an AC power source 26 in electrical communication with the members (col. 5, lines 3-22). However, it would appear the function of the AC power source is for the establishing of an appropriate field gradient (see col. 2-4). Hofmann does not explicitly disclose that the sample holder be adapted for relative movement from a first position to the second position as set forth by the claims. However, configuring a analyte manipulation device such that it could be utilized for a plurality of different containers (i.e. that it can pulled in and out of a particular analyte container) is notoriously well known in the art. In particular, Dahms discloses in an alternate separation device that structure for the manipulation of a particular sample may be configured such that the said structure is useable on a plurality of different sample containing vessels thereby facilitating automated analyzing (fig. 2-4 and abstract). Said structure must be adapted so that it can be moved from first and second positions (i.e. it must be raised and lowered into and out of the vessel currently being analyzed) via motors (col. 9, lines 17-20). Alternatively, the turntable of Dahm (indicated by the arrows of fig. 3 and 6) moves the analyte holders through different positions such that the different analyte holders can be aligned with the said structure. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the structure of Dahms for the device of Hofmann in order to allow a particular analyte structure to be useable for a plurality of different sample holders and to automate the analysis of the analyte.

6. With respect to claim 2, see Dahms (col. 9, lines 17-20).

7. With respect to claim 3, the turntable of Dahms moves the analyte holder toward and away from the manipulating structure (which in Hofmann are electrically conducting members).

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8. With respect to claim 4 (those limitations not addressed above for claim 1), the moveable support of Dahm (col. 4, lines 17-20) supports the said analyzing structure (which in Hofmann are electrically conducting members). With respect to trapping a portion of a polarizable analyte in a concentration zone, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. However, that does appear to be the function of the device of Hofmann (see col. 2-4).

9. With respect to claims 8 and 9, the electrically conducting members of Hofmann inherently possesses edges or corners.

10. With respect to claim 11, an innumerable number of features of either Hofmann or Dahms could reasonably be utilized to function as a handle for holding the device.

11. With respect to claim 12, see figure 4 of Dahms.

12. Claims 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann and Dahms as applied to claim 4 above, and further in view of Goldstein (USP 4,643,814).

13. With respect to the claims, Hofmann and Dahms disclosed all the limitations of the claims, but did not explicitly recite the presence of either resin material or non-conductive filament within the members. Goldstein teaches in an alternate separation device teaches that materials can be placed between electrically conductive members to facilitate the holding of the desired analyte material (col. 4, line 53 through col. 5, line 38). Among the materials contemplated include epoxy resin (col. 12, lines 5-10) and porous non-conductive filaments (e.g. see col. 4, lines 53-66). It would have been obvious to one of ordinary skill in the art at the time

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the invention was being made to utilize the teaching of Goldstein for the apparatus of Hofmann and Dahms in order to hold the materials that are being sorted.

14. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hofmann in view of Dahm as applied to claim 4 above, and further in view of WO 97/41219 (hereafter "WO '219").

15. The references set forth all the limitations of the claim, but did not explicitly recite the addition of a DC power source for the electrically conducting members. WO '219 teaches that the use of DC voltages allows one to capture DNA from an analyte solution thereby allowing said DNA to be removed from the solution and later replicated or amplified (p. 1, lines 15-24). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of WO '219 for the device of Hofmann and Dahm in order to capture the sorted DNA allowing said DNA to be replicated or amplified.

Response to Arguments

16. Applicant's arguments filed 2-6-2004 have been fully considered but they are not persuasive. Applicant first traverses the examiner's statement about configuring a manipulation device so as to be utilized for a plurality of containers being "well-known" is not instructive. However, this generalization in question was only the lead-in to a *specific demonstration* of that principle with Dahms. With respect to Dahms, applicant urges that Dahms might show the desirability of configuring a sampler tube. However, applicant appears to be delving into the minutia of Dahms while ignoring the larger issue that was the focus of the rejection. In particular, the teaching of Dahms is drawn to the concept of automating an analysis system so

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that a particular analysis can be performed on a plurality of samples. More broadly, Dahms is drawn to the concept of being able to simply move a particular analysis into and out of a particular container. Whether Dahms utilized sampling tubes or is drawn to a different type of analysis is all irrelevant in view of what Dahms is being utilized to show. Because Hofmann already set forth that an electrode system is to be placed into a particular container (col. 5, lines 24-26), the only remaining question is whether one possessing ordinary skill in the art have been motivated to allow the electrode system to be moved into and out of the container. Dahms show a way that an analysis system can be configured to allow it to be inserted into a particular container and subsequently removed. Applicant's position essentially appears to be that one possessing ordinary skill in the art would not have been motivated to allow the electrodes of Hofmann be movable into and out of a container. However, case law has already established that the simply making the prior art adjustable does not impart patentability over the prior art. See *In re Stevens*, 101 USPQ 284 (CCPA 1954).

17. The applicant also urges that the "wherein" clauses of claims 1 and 4 do not merely recite intended use of the device. In view of that assertion, the examiner is in agreement and has withdrawn the statement concerning intended use above. However, the examiner would contend that Hofmann would be capable of trapping analyte or establishing a field gradient as claimed. On this issue, applicant applicant urges that Hofmann appears to lack structure for establishing an electric field gradient. In particular, applicant urges that a magnetic coil "must" surround the region between the electrodes. First, where does it state in the claims that the electric field gradient must perform its trapping without the assistance of a magnetic field? The claims are constructed with open language (i.e. "comprising"), and there is nothing in the claims that forbid

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the "trapping" to be augmented with other means. Second, the examiner is confused by applicant's argument that because a magnetic field is being utilized, Hofmann must not have established an effective gradient. That doesn't logically follow. Hofmann appears to rely on the movement or sorting imparted by a combination of electric and magnetic fields. Each field appears to impart on the particles a particular movement and the result of that combination of movement determines how the particle moves. See equation 9 of Hofmann that shows that the movement of a particles ultimately depend on the magnitude of the electric field. Finally, even if Hofmann did not recognize that an electric field alone was capable of generating a field gradient sufficient for trapping of particles, the claims are drawn to an apparatus. Even if the applicant have discovered new reason for using a particular structure (i.e. trapping of analyte), it has been well established that an apparatus patent cannot be granted for the discovery of a new reason for utilizing structure that was already old in the art.

18. Applicant also argues that Hofmann relies on flat electrode surfaces and that would appear to result in uniform electric fields. First, this would appear to contradict applicant's embodiment of fig. 5A-5C where applicant is apparently utilizing flat electrodes. If fact, applicant doesn't appear to ever place any criticality on the shape of the electrodes indicating that any number of shapes of electrodes can successfully provide the desired electric field gradient, assuming one applies the appropriate oscillating electric field. Second, applicant appears to be interpreting a uniform electric field as not containing a gradient. This does not appear to be correct. The field of Hofmann (or the instant invention for that matter) can be uniform and still have a gradient. In any AC electric field, the strength of that field will vary

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depending on the position between the electric field generating electrodes, and that positional variance would read on the claim term "electric field gradient".

Conclusion

19. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 6:30 A.M. to 4:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'Kaj Olsen', with a long horizontal flourish extending to the right.

Kaj Olsen Ph.D.
Primary Examiner
AU 1753
May 4, 2004